

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alexandra, Virginia 22313-1450 www.unpto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/528,103	10/03/2005	Hartmut Schlueter	Merk-3002	9112	
23599 7590 (8805/2008) MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITI: 1400 ARLINGTON, VA 22201			EXAM	EXAMINER	
			THERKORN, ERNEST G		
			ART UNIT	PAPER NUMBER	
			1797		
			MAIL DATE	DELIVERY MODE	
			08/05/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/528,103 SCHLUETER, HARTMUT Office Action Summary Examiner Art Unit Ernest G. Therkorn 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 06 June 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-7 and 10 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SZ/UE)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date. \_\_\_\_\_\_.

6) Other:

Notice of Informal Patent Application

10/528,103 Art Unit: 1797

Claims 1-7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support for limiting the claims to "elution chromatography" can be found. No support for the phase "whereby suitable .... are ascertained" can be found. No support for precluding displacement chromatography parameters can be found. As such, the claims are considered to be drawn to new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filled in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 10 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cramer (U.S. Patent Publication No. 2001/0047086). The claims are considered to read on Cramer (U.S. Patent

10/528,103 Art Unit: 1797

Publication No. 2001/0047086). However, if a difference exists between the claims and Cramer (U.S. Patent Publication No. 2001/0047086), it would reside in optimizing the steps of Cramer (U.S. Patent Publication No. 2001/0047086). It would have been obvious to optimize the steps of Cramer (U.S. Patent Publication No. 2001/0047086) to enhance separation.

Claims 1-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160). At best, the claims differ from Cramer (U.S. Patent Publication No. 2001/0047086) in reciting elution chromatography. Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem. It would have been obvious that Cramer (U.S. Patent Publication No. 2001/0047086)'s method would reveal suitable elution chromatography parameters because Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) in view of Welch (U.S. Patent No. 6,342,160) as applied to claims 1-7 and 10 above, and further in view of each of MacPhee (U.S. Patent No.

10/528,103 Art Unit: 1797

2003/0161753), Snyder (U.S. Patent Publication No. 2005/0182242), and Pantoliano (U.S. Patent No. 6,214,293). At best, the claim differs from either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) in reciting use of a stabilizer. MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. Pantoliano (U.S. Patent No. 6.214.293) (column 6. lines 11-24 and column 57. lines 25-31) discloses glycerol stabilizes protein. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) because MacPhee (U.S. Patent No. 2003/0161753) (paragraph 38, lines 3, 19, 20, and 32) discloses stabilizing biological materials with glycerol reduces damage to the biological material. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) because Snyder (U.S. Patent Publication No. 2005/0182242) (paragraphs 120 and 121) discloses that glycerol stabilizes protein. It would have been obvious to use a stabilizer in either Cramer (U.S. Patent Publication No. 2001/0047086) or Cramer (U.S. Patent Publication No. 2001/0047086) because Pantoliano (U.S. Patent No. 6,214,293) (column 6, lines 11-24 and column 57, lines 25-31) discloses glycerol stabilizes protein.

The remarks urge patentability over Cramer (U.S. Patent Publication No. 2001/0047086) based upon its disclosure of displacer molecules. However, excluding

10/528,103 Art Unit: 1797

ascertaining displacer parameters is considered to be new matter. In any event, since all the claimed steps are the same as Cramer (U.S. Patent Publication No. 2001/0047086), the results, i.e., ascertaining elution chromatography parameters, must be the same. Alternatively, Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem. It would have been obvious that Cramer (U.S. Patent Publication No. 2001/0047086)'s method would reveal suitable elution chromatography parameters because Welch (U.S. Patent No. 6,342,160) (Figure 15, column 3, lines 15-17, column 2, lines 24-35, column 3, lines 38-40, and column 6, line 50 and 65-67) discloses that use of an array of different media with sample allows for the selection of a highly selective adsorbent for a given separation problem.

The remarks urge patentability based upon automation. Cramer (U.S. Patent Publication No. 2001/0047086) discloses automation on paragraph 53, lines 4-5 and Welch (U.S. Patent No. 6,342,160) discloses automation on column 4, lines 52-53.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

10/528,103 Art Unit: 1797

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernest G. Therkorn/ Ernest G. Therkorn Primary Examiner Art Unit 1797

EGT August 1, 2008